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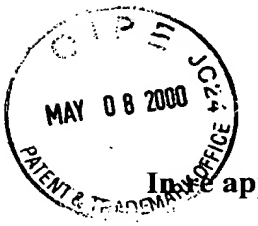

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Davis
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(NE)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Cook

Serial No.: 08/877,317 Group Art Unit: 1633

Filed: June 17, 1997 Examiner: J. Martinell

For: PNA-DNA-PNA CHIMERIC MACROMOLECULES

I, Gregory L. Hillyer, Registration No. 44,154 certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

On May 5, 2000

Gregory L. Hillyer, Registration No:44,154

Assistant Commissioner
for Patents
Washington, D.C. 20231

REQUEST FOR RECONSIDERATION

This is responsive to the Final Office Action mailed on February 16, 2000, in connection with the above-identified patent application.

Claims 13-16, 19, 20, and 24-26 are pending in this patent application.

All pending claims stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. Applicant respectfully requests reconsideration of this rejection as there is no evidence or reasoning to support the Examiner's subjective belief that those skilled in the art could not make and use the invention to at least some measurable degree.

The Office Action mistakenly alleges that Applicant's specification does not adequately teach an effect on an organism through the administration of any of the modified PNAs set forth in the claims. The specification at, for example, page 5, lines 33 to 35 and page 8, lines 25-30 explains that one such effect is the modulation of the production of an undesired protein that results when one contacts an organism with a macromolecule of the present invention having a sequence of nucleobases capable of hybridizing to a complementary strand of nucleic acid.

Although the Office Action purportedly questions the effect that modified PNAs have on an organism, the rejection appears to actually be predicated on the subjective belief that therapeutic data is required to "adequately teach" that effect. The patent laws, however, do not require such data. The first paragraph of Section 112, for example, requires nothing more than objective enablement. The particular means through which an applicant chooses to enable the practice of his invention, either by the use of illustrative examples or by broad terminology, is of no importance. *In re Marzocchi and Horton*, 169 U.S.P.Q. 367 (C.C.P.A. 1971) (emphasis added).

When the present specification is judged in light of the proper test for enablement, it is clear that Applicant has provided extensive teachings as to how to make and how to use the claimed compounds. It is in this regard that the teachings of Rojanasakul, *Advanced Drug Delivery Reviews*, 18, 115-131 (1996) ("the Rojanasakul reference") are relevant to the present discussion of enablement. The Rojanasakul reference states that

> [s]everal ON drugs have already demonstrated enough promise to justify clinical trials. They are being tested in patients suffering from leukemia, AIDS, and other diseases in which improved treatments are necessary. It is expected that in the future

> these ON drugs will be commonly used to treat those diseases for which no effective therapies yet exist.

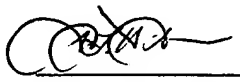
See, the Rojanasakul reference at page 126. This passage serves as compelling evidence that the state of the art of oligonucleotide therapeutics, at the time the present application was filed, was such that an artisan could readily obtain at least some measurable test results once armed with the teachings of the present application.

The Examiner pointedly has failed to address this disclosure in the Rojanasakul reference, and instead cites it for its alleged disclosure of "problems" encountered in connection with the therapeutic use of oligonucleotides. The Examiner, however, is not permitted to ignore the above-quoted text establishing that several oligonucleotidic drugs have initiated clinical trials or the fact that his alleged "problems" would not prevent the presently claimed methods from producing measurable results.

Although the Office Action criticizes Applicant for not addressing each and every alleged "problem," what the Office Action fails to recognize is that because it is ***undisputed*** that the claimed methods would produce measurable results, Applicant has absolutely no burden to do so. There is simply no requirement that an applicant overcome all potential obstacles faced when practicing an invention or that an invention be problem-free to be enabled. As discussed in detail in the response dated December 30, 1999, it is improper for the PTO to require any showing regarding the degree of effectiveness of therapeutic inventions. M.P.E.P. § 2107.02; *In re Sichert,* 566 F.2d 1154 (C.C.P.A. 1977).

In view of the foregoing, the disclosure of the Rojanasakul reference fails to adequately support the present rejection of Applicant's claims. Since such support would be required for a proper rejection based on a lack of enablement, Applicant respectfully requests that the rejection under §112, first paragraph, be reconsidered and withdrawn.

Respectfully submitted,



Gregory L. Hillyer
Registration No. 44,154

Date: May 5, 2000
WOODCOCK WASHBURN KURTZ
MACKIEWICZ & NORRIS
One Liberty Place - 46th Floor
Philadelphia, PA 19103
(215) 568-3100